DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

4859 '00 JAN 28 P2:37

JAN 13 2000

S. W. Flowers
Chief Executive Officer
ShmsHrs, Inc.
PO Box 539
Maplewood, New Jersey 07040

Dear Mr. Flowers:

This is in response to your letter, dated October 7, 1999, to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that ShmsHrs, Inc. is making the following statement for its product "Relief":

> "For itching, burning, and heat disorders get..."
> "For damp & heat problems characterized by symptoms like burning, itching, heat, blisters, and discharge. Especially useful for problems in and around the genitalia, urinary tract, and rectum."

This letter is similar in content to your letter received by FDA on September 20, 1999 and which we responded to in a letter dated September 28, 1999.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggests that it is intended to prevent, treat, cure, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

LET327

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

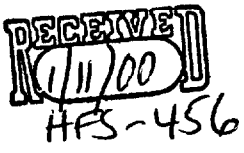
Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, New Jersey District Office, Office of Compliance, HFR-MA340

cc:
HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-456 (File)
HFS-450 (file, r/f)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-605
GCF-1 (Nickerson, Dorsey, Barnett)
HFV-228 (SBenz)
f/t:HFS-456:rjm:1/12/99:docname:shmshrs.adv:disc43

ShmsHrs, Inc.

PO Box 539

Maplewood, NJ 07040



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10/7/99

To: Food and Drug Administration /HFE-88, Rockville MD 20857

From: ShmsHrs Corp./ S.W. Flowers, Chief Executive Officer

Re: New Dietary Supplement RELIEVE / RELIEF

In accordance with the "FDA Guide to Dietary Supplements" we are informing you of the release of our herbal product with the following structure function claim:

"For itching, burning, and heat disorders get ..."

"For damp & heat problems characterized by symptoms like burning, itching, heat, blisters, and discharge. Especially useful for problems in and around the genitalia, urinary tract, and rectum."

We have applied your mandatory disclaimer to the label:

"This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."

"Consult your physician before using."

However, marketing consultants have recommended minor labeling changes and the use of the product name RELIEF.